Complete Summary

GUIDELINE TITLE

American Society of Clinical Oncology recommendations on fertility preservation in cancer patients.

BIBLIOGRAPHIC SOURCE(S)

Lee SJ, Schover LR, Partridge AH, Patrizio P, Wallace WH, Hagerty K, Beck LN, Brennan LV, Oktay K. American Society of Clinical Oncology recommendations on fertility preservation in cancer patients. J Clin Oncol 2006 Jun 20;24(18):1-15. [167 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Fertility/Infertility
Cancer

GUIDELINE CATEGORY

Counseling
Treatment

CLINICAL SPECIALTY

Oncology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide guidance to oncologists about available fertility preservation methods and related issues in cancer patients

TARGET POPULATION

Men, women, and children with cancer who are of reproductive age and are at risk for treatment-related infertility

INTERVENTIONS AND PRACTICES CONSIDERED

Preservation of Male Fertility

1. Sperm cryopreservation after masturbation or alternative methods of collection
2. Gonadal shielding during radiotherapy
3. Testicular tissue cryopreservation, testis xenografting, or spermatogonial isolation (Note: This intervention has not been tested in humans)
4. Hormonal gonadoprotection (considered but not recommended)

Preservation of Female Fertility

1. Embryo cryopreservation
2. Oocyte cryopreservation
3. Ovarian cryopreservation and transplantation
4. Gonadal shielding during radiotherapy
5. Ovarian transposition
6. Trachelectomy
7. Minimization of normal tissue resection
8. Hormonal therapies to protect ovarian tissue

Also Considered

1. Preservation of fertility in postpubertal and prepubertal children
2. Talking points and referral guidelines for oncologists

MAJOR OUTCOMES CONSIDERED

Primary outcomes of interest included:

- Pregnancies
- Live births

The following were also considered:

- Fertility maintenance
- Resumption/maintenance of menses
- Number of oocytes recovered
- Number of embryos recovered
- Fertilization rates
- In vitro fertilization (IVF) outcome
- Risks associated with the fertility intervention
- Quality of life
- Patient and/or family satisfaction
- Patient education or increased awareness
- Economic evaluation (e.g., cost-effectiveness, cost utility)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The following electronic databases were searched from 1987 through March 2005: MEDLINE, PreMEDLINE, and the Cochrane Collaboration Library. The National Cancer Institute's (NCI) PDQ database of clinical trials, and the National Library of Medicine's (NLM) *ClinicalTrials.gov* database were also searched for ongoing trials. Results were supplemented with hand searching of selected reviews and personal files. The following MeSH terms and text words were used in a core search: "fertility," "infertility," and "neoplasms." In separate searches, results were cross-referenced with "pregnancy," "pregnancy outcomes," "reproductive techniques," "premature ovarian failure," and "premature menopause." Supplemental searches were done for each intervention using terms specific for that intervention (eg, "sperm banks," "semen preservation"). Due to the very limited number of randomized controlled trials in this field of research, study design was not limited to randomized controlled trials, but was expanded to include cohort designs, case series, and where no other data were available, case reports and selected abstracts. Letters, commentaries, and editorials were excluded.

Articles were selected for inclusion in the systematic review of the evidence if they met the following criteria: (1) the study discussed a fertility intervention and reported primary data; and (2) the study population consisted of cancer patients scheduled for or undergoing cancer treatments that threaten fertility (other populations could be considered where data were lacking in cancer patients). Articles were excluded from further consideration if they did not report specifically on a fertility intervention and did not report primary data. However, due to the limited nature of the data in many areas, the Panel made an a priori decision to also retain high-quality reviews or background papers, and these articles were described as such in the coding process.

An initial article abstract screen was performed by the American Society of Clinical Oncology (ASCO) staff. The ASCO Panel reviewed all remaining potentially relevant abstracts identified in the original literature searches to select studies pertinent to its deliberations. Two Panel members independently reviewed each abstract for its relevance to the clinical questions, and disagreements were resolved by third-party review.

NUMBER OF SOURCE DOCUMENTS

Preliminary searches identified 1,675 potential articles. The initial abstract screen performed by the American Society of Clinical Oncology (ASCO) staff eliminated 807 abstracts that failed to meet any of the inclusion criteria. The ASCO Panel conducted dual independent review of all remaining 868 potentially relevant abstracts identified in the original systematic review. The Panel eliminated 463 abstracts at this stage of the review; the remaining 405 articles were reviewed in full for the interventions and outcomes described above. One hundred twenty-nine articles that did not report primary data on a fertility preserving intervention were excluded from further consideration. Two hundred thirty-three articles met the inclusion criteria, and an additional 43 articles met the a priori criteria as supplementary studies or reviews.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Full text articles were reviewed for all selected abstracts. The Panel designed a coding sheet to complete the review of identified potentially relevant studies, and the Co-Chairs assigned each Panel member a subset of articles to review. Data were extracted on the source of the threat to fertility, the intervention being considered, the outcomes assessed, the number of patients and types of cancer, and study design.

A meta-analysis was not performed because the studies were judged to be too small and heterogeneous for meaningful quantitative synthesis.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The entire Panel participated in monthly teleconferences. Preliminary teleconferences refined the questions addressed by the guideline; subsequent teleconferences addressed the process of the systematic review and the allocation of writing assignments for respective sections. All members of the Panel participated in the preparation of the guideline.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Studies document that some physicians believe that the cost of fertility preservation interventions is prohibitive. For example, 51% of oncologists in a United States study believed that most men could not afford to bank sperm because of out-of-pocket costs. However, oncologists overestimated these costs and their deterrent effect; in a companion survey of young men, only 7% cited financial reasons for not banking sperm.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Feedback from external reviewers was solicited. The content of the guideline and the manuscript were reviewed and approved by the Health Services Committee (HSC) and by the American Society of Clinical Oncology (ASCO) Board of Directors before dissemination.

Comparison with Guidelines for Other Groups

Consensus statements have also been developed by some professional societies, including the British Fertility Society (http://www.britishfertilitysociety.org.uk/practicepolicy/documents/fccpaper.pdf), the European Society of Human Reproduction and Embryology (ESHRE) Task Force (http://www.eshre.com), and the American Society for Reproductive Medicine. The Panel has evaluated the Guidelines produced by reproductive specialist societies and found them to be consistent with the ASCO guidelines.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Oncologists should address the possibility of infertility with patients treated during their reproductive years. Fertility preservation is often possible, but to preserve the full range of options, fertility preservation approaches should be considered as early as possible during treatment planning.

Summary of Fertility Preservation Options in Males

Intervention	Definition	Comment	Considerations
Sperm cryopreservation (S) after masturbation	Freezing sperm obtained through masturbation	The most established technique for fertility preservation in men; large cohort studies in men with cancer	• Outpatient procedure • Approximately $1,500 for three samples stored for 3 years, storage fee for additional years*
Sperm cryopreservation (S) after alternative methods of sperm collection	Freezing sperm obtained through testicular aspiration or extraction, electroejaculation under sedation, or from a post-masturbation urine sample	Small case series and case reports	Testicular sperm extraction outpatient surgical procedure
Gonadal shielding during radiation therapy (S)	Use of shielding to reduce the dose of radiation delivered to the testicles	Case series	• Only possible with selected radiation fields and anatomy • Expertise is required to ensure shielding does not increase dose delivered to the reproductive organs
Testicular tissue cryopreservation; Testis xenografting; Spermatogonial	Freezing testicular tissue or germ cells and reimplantation after cancer	Has not been tested in humans; successful application in	Outpatient surgical procedure

Intervention	Definition	Comment	Considerations
isolation (I)	treatment or maturation in animals	animal models	
Testicular suppression with gonadotropin-releasing hormone (GnRH) analogs or antagonists (I)	Use of hormonal therapies to protect testicular tissue during chemotherapy or radiation therapy	Studies do not support the effectiveness of this approach	

Abbreviations: S, standard; I, investigational

*Costs are estimates.

Quality of Evidence Supporting Current and Forthcoming Options for Preservation of Fertility in Males

Sperm cryopreservation. Sperm cryopreservation is effective, and oncologists should discuss sperm banking with appropriate patients. It is strongly recommended that sperm be collected before initiation of cancer therapy because the quality of the sample and sperm DNA integrity may be compromised even after a single treatment session. Although planned chemotherapy may limit the number of ejaculates, intracytoplasmic sperm injection allows the successful freezing and future use of a very limited amount of sperm.

Hormonal gonadoprotection. Hormonal therapy in men is not successful in preserving fertility when highly sterilizing chemotherapy is administered.

Other considerations. Men should be advised of a potentially higher risk of genetic damage in sperm stored after initiation of therapy. Testicular tissue or spermatogonial cryopreservation and transplantation or testis xenografting have not yet been tested successfully in humans. Of note, such approaches are also the only methods of fertility preservation potentially available to prepubertal boys.

Fertility Preservation Options in Females

Intervention	Definition	Comment	Considerations*
Embryo cryopreservation (S)	Harvesting eggs, in vitro fertilization (IVF), and freezing of	The most established technique for fertility preservation in	• Requires 10-14 days of ovarian stimulation from the beginning of menstrual cycle

Intervention	Definition	Comment	Considerations*
	embryos for later implantation	women	• Outpatient surgical procedure • Requires partner or donor sperm • Approximately $8,000 per cycle, $350 per year storage fees
Oocyte cryopreservation (I)	Harvesting and freezing of unfertilized eggs	Small case series and case reports; as of 2005, 120 deliveries reported, approximately 2% live births per thawed oocyte (3-4 times lower than standard IVF)	• Requires 10-14 days of ovarian stimulation from the beginning of menstrual cycle • Outpatient surgical procedure • Approximately $8,000 per cycle, $350/yr storage fees
Ovarian cryopreservation and transplantation (I)	Freezing of ovarian tissue and reimplantation after cancer treatment	Case reports; as of 2005, two live births reported	• Not suitable when risk of ovarian involvement is high • Same day outpatient surgical procedure
Gonadal shielding during radiation therapy (S)	Use of shielding to reduce the dose of radiation delivered to the reproductive organs	Case series	• Only possible with selected radiation fields and anatomy • Expertise is required to ensure shielding does not increase dose delivered to the reproductive organs
Ovarian transposition	Surgical repositioning of	Large cohort studies and	• Same day outpatient surgical

Intervention	Definition	Comment	Considerations*
(oophoropexy) (S)	ovaries away from the radiation field	case series suggest approximately 50% chance of success due to altered ovarian blood flow and scattered radiation	procedure • Transposition should be performed just before radiation therapy to prevent return of ovaries to former position • May need repositioning or IVF to conceive
Trachelectomy (S)	Surgical removal of the cervix while preserving the uterus	Large case series and case reports	• Inpatient surgical procedure • Limited to early stage cervical cancer; no evidence of higher cancer relapse rate in appropriate candidates • Expertise may not be widely available
Other conservative gynecologic surgery (S/I)	Minimization of normal tissue resection	Large case series and case reports	• Expertise may not be widely available
Ovarian suppression with GnRH analogs or antagonists (I)	Use of hormonal therapies to protect ovarian tissue during chemotherapy or radiation therapy	Small randomized studies and case series. Larger randomized trials in progress	• Medication given before and during treatment with chemotherapy • Approximately $500/mo

Abbreviations: S, standard; I, investigational; IVF, in vitro fertilization

*Costs are estimates

Quality of Evidence Supporting Current and Forthcoming Options for Preservation of Fertility in Females

Embryo cryopreservation. Embryo cryopreservation is considered an established fertility preservation method because it has routinely been used for storing surplus embryos after in vitro fertilization. Approximately 2 weeks of ovarian stimulation with daily injections of follicle-stimulating hormone is required and must be started within the first 3 days of the menstrual cycle.

Cryopreservation of unfertilized oocytes. Cryopreservation of unfertilized oocytes is an option, particularly for patients without a partner or those with religious or ethical objections to embryo freezing. Ovarian stimulation is required as described in the preceding section. Oocyte cryopreservation should only be performed in centers with the necessary expertise, and the Panel recommends participation in institutional review board (IRB)-approved protocols.

Ovarian tissue cryopreservation. Ovarian tissue cryopreservation and transplantation procedures should be performed only in centers with the necessary expertise under IRB-approved protocols that include follow-up for recurrent cancer. A concern with reimplanting ovarian tissue is the potential for reintroducing cancer cells, although in fewer than 20 procedures reported thus far, there are no reports of cancer recurrence.

Ovarian suppression. Currently, there is insufficient evidence regarding the safety and effectiveness of GnRH analogs and other means of ovarian suppression on fertility preservation. Women interested in this technique are encouraged to participate in clinical trials.

Ovarian transposition. Ovarian transposition (oophoropexy) can be offered when pelvic radiation is administered as cancer treatment. Because of the risk of remigration of the ovaries, this procedure should be performed as close to the radiation treatment as possible.

Conservative gynecologic surgery. It has been suggested that radical trachelectomy be restricted to stage IA2-IB disease with diameter less than 2 cm and invasion less than 10 mm. In the treatment of other gynecologic malignancies, interventions to spare fertility have generally centered on doing less-radical surgery and/or lower-dose chemotherapy with the intent of sparing the reproductive organs as much as possible.

Other considerations. Of special concern in breast and gynecologic malignancies is the possibility that fertility preservation interventions and/or subsequent pregnancy may increase the risk of cancer recurrence. Although several studies have not shown a decrement in survival or an increase in risk of breast cancer recurrence with pregnancy, the studies are all limited by significant biases, and concerns remain for some women and their physicians.

Special Considerations: Fertility Preservation in Children

Use of established methods of fertility preservation (semen cryopreservation and embryo freezing) in postpubertal minor children requires patient assent and parental consent. The modalities available to prepubertal children to preserve their fertility are limited by the sexual immaturity of the children and are essentially experimental. Efforts to preserve fertility of children using

experimental methods (e.g., gonadal tissue cryopreservation) should be attempted only under IRB approved protocols.

The Role of the Oncologist in Advising Patients About Fertility Preservation Options

As with other potential complications of cancer treatment, oncologists have a responsibility to inform patients about the risk that their cancer treatment will permanently impair fertility. An algorithm for triaging fertility preservation referrals is presented in the original guideline document and suggested talking points are illustrated in a sidebar.

Oncologists should answer basic questions about whether fertility preservation options decrease the chance of successful cancer treatment, increase the risk of maternal or perinatal complications, or compromise the health of offspring. Patients should be encouraged to participate in registries and clinical studies as available to define further the safety of these interventions and strategies. Currently, women with a history of cancer and cancer treatment should be considered high risk for perinatal complications and would be prudent to seek specialized perinatal care.

Oncologists should refer interested and appropriate patients to reproductive specialists as soon as possible. Referral to psychosocial providers may be beneficial when a patient has moderate to severe distress about potential infertility.

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for Triage of Fertility Preservation Referrals.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Most recommendations are supported by case reports, case series, and cohort studies. Only a few randomized or definitive trials were found in the literature review.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate fertility preservation approaches in people undergoing treatment for cancer

POTENTIAL HARMS

- Delay in cancer treatment (early referral to a subspecialist can minimize this delay)

- Risk of tumor recurrence
- Potential negative (physical and psychological) effects of fertility preservation attempts

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Guidelines cannot always account for individual variation among patients. Guidelines are not intended to supplant physician judgment with respect to particular patients or special clinical situations and cannot be considered inclusive of all proper methods of care or exclusive of other treatments reasonably directed at obtaining the same result. The American Society of Clinical Oncology (ASCO) considers adherence to these guidelines to be voluntary, with the ultimate determination regarding their application to be made by the physician in light of each patient's individual circumstances. In addition, these guidelines describe the use of procedures and therapies in clinical practice; they cannot be assumed to apply to the use of these interventions performed in the context of clinical trials, given that clinical studies are designed to evaluate or validate innovative approaches in a disease for which improved staging and treatment is needed.
- Review of the fertility preservation literature reveals a paucity of large and/or randomized studies. Most data come from cohort studies, case series, small nonrandomized clinical trials or case reports. Fertility preservation methods are still applied relatively infrequently in the cancer population, limiting greater knowledge about success and effects of different potential interventions. Other than risk of tumor recurrence, less attention is paid to the potential negative effects (physical and psychological) of fertility preservation attempts.
- Little is known about the emotional impact of infertility or utilization of fertility preservation options on cohorts that are diverse in ethnicity and socioeconomic status, groups that face even greater barriers to fertility preservation.
- The Panel encourages additional well-designed studies evaluating methods of fertility preservation in people with cancer to help answer these questions. However, the Panel also notes that the traditional gold standard of randomized, controlled, and blinded therapeutic studies may not be possible in this area.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources
Personal Digital Assistant (PDA) Downloads
Quick Reference Guides/Physician Guides
Slide Presentation

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Lee SJ, Schover LR, Partridge AH, Patrizio P, Wallace WH, Hagerty K, Beck LN, Brennan LV, Oktay K. American Society of Clinical Oncology recommendations on fertility preservation in cancer patients. J Clin Oncol 2006 Jun 20;24(18):1-15. [167 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Jun 20

GUIDELINE DEVELOPER(S)

American Society of Clinical Oncology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society of Clinical Oncology

GUIDELINE COMMITTEE

American Society of Clinical Oncology (ASCO) Expert Panel

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Although all authors completed the disclosure declaration, the following authors or immediate family members indicated a financial interest.

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*No significant financial relationships to disclose.

No conflict exists for drugs or devices used in a study if they are not being evaluated as part of the investigation. For a detailed description of the disclosure categories, or for more information about American Society of Clinical Oncology's (ASCO's) conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Society of Clinical Oncology (ASCO) Web site.

Print copies: Available from American Society of Clinical Oncology, Cancer Policy and Clinical Affairs, 1900 Duke Street, Suite 200, Alexandria, VA 22314; E-mail: guidelines@asco.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- ASCO recommendations on fertility preservation in cancer patients: guideline summary. Alexandria (VA): American Society of Clinical Oncology; 2006 May. 4 p. Electronic copies: Available in Portable Document Format (PDF) from the American Society of Clinical Oncology (ASCO) Web site.
- ASCO recommendations on fertility preservation in people treated for cancer: fertility preservation options & discussion points. Alexandria (VA): American Society of Clinical Oncology; 2006. 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American Society of Clinical Oncology (ASCO) Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site.
- Fertility preservation in people treated for cancer. Slide set. 2006. 50 p. Electronic copies: Available in Portable Document Format (PDF) from the ASCO Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site.

Guidelines are available for Personal Digital Assistant (PDA) download from the ASCO Web site.

PATIENT RESOURCES

The following is available:

- ASCO patient guide: fertility preservation. 2006 May. 3 p. Available in Portable Document Format (PDF) from the Cancer.Net Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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